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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/742,008	Applicant(s) VISKOV, CHRISTIAN	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 22 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-14 and 22-23, and the compound of Example 1, [(R)-2-(N,N-dimethylamino)ethylthio-Sar]³-[4'-hydroxy-MeLeu]⁴-cyclosporin A. in the response filed January 28, 2005, is acknowledged. The traversal is on the ground(s) that Examiner has not shown that there would be serious burden to search the claims of Group I-V since all of the method of use claims recites using a compound of formula I; and all five groups are classified in class 514. Applicants' response has been considered, however, the argument is not found persuasive because coexamination of Groups II-V claims would require search of subjects unnecessary for the examination of Group I, e.g., various diseases such as a retrovirus infection or an associated syndrome, a chronic inflammatory disease, an autoimmune disease or inflammation, schistosomiasis, filariasis, leishmaniasis, coccidioidomycosis and malaria. Therefore, coexamination of Groups II-V would require a serious additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

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The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 4, 14 and 23 are objected to because the claim contains recitation of cyclosporins with non-elected R₁, R₂, R₄ to R₁₁, and Z₁, Z₂ and Z₄-Z₁₁ groups.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 1-14 and 22 are indefinite because of the use of the term "cyclosporin derivative". The term cited renders the claim indefinite, it is not clear how different the derivative is from its parent compound, and what structure the derivative has. Claims 2-12, 14 and 22 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.
5. Claim 3 is indefinite because of the use of "formula (I)", which does not show the backbone structure of cyclosporin, it is not clear what the formula (I) represents.
6. Claims 13 and 14 are indefinite because of the use of the term "if any" or "which may possibly interfere". The term cited renders the claim indefinite, it is not clear whether the limitation following the term is part of the claim. Claim 14 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

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7. Claim 22 recites the limitation " R_i in formula (IIIb)" in line 1. There is insufficient antecedent basis for this limitation in claim 1, which claim 22 depends from.

Conclusion

8. Claims 1-14 and 22 are rejected, and claim 23 is objected to.

Art of Record

Seebach (EP 194972, an English equivalent, U.S. Patent 4,703,033) teaches a cyclosporin derivative modified at the 3 position can be obtained by first reacting a cyclosporin with an alkali metal amide to form a polyanion of the cyclosporin, which then reacts with electrophilic agent to give the cyclosporin derivative. However, the reference does not teach a method of preparing a cyclosporin derivative via a polyanion intermediate that is obtained by reacting a cyclosporin with a hexamethyldisilazane metal salt.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

July 8, 2005